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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,729	08/03/2001	Steven Kiyoshi Yoshinaga	A-579B	7722

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,729	YOSHINAGA, STEVEN KIYOSHI	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/16/05; 6/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 06/16/2006 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/16/2006 has been entered.

2. Applicant's amendment/remarks, filed 06/16/2006, are acknowledged.

Claims 1 – 32 have been cancelled previously.
Claims 33 – 37, 42 – 44, and 46 – 47 have been amended.

Claims 33 – 54 are pending and under consideration.

3. This Office Action will be in response to applicant's arguments, filed 06/16/2006.

The rejections of record can be found in the previous Office Action, mailed 08/08/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

It is noted that New Grounds of Rejection are set forth herein.

4. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

5. Upon further review, it is determined that this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but fails to comply with the requirements of 37 CFR 1.821 through 1.825, for the reasons set forth herein.

A. Upon review of the instant application, it is noted that the sequences disclosed at least in Figures 1 – 3 and 12 – 13 *are not accompanied by SEQ ID Numbers*. Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules. Applicant is reminded to amend the specification and the claims accordingly. The SEQ ID Numbers for a sequence shown in a drawing may be incorporated either as part of the drawing or in the Brief Description of the drawing.

B. In the Sequence Listing, the source organism of SEQ ID NOS: 11 and 12 is listed as *Mus musculus*; however, SEQ ID NOS: 11 and 12 appear to be subsequences of SEQ ID NOS: 16 and 17, respectively, which are listed as human. Appropriate correction or clarification is required. For examination purposes, all of SEQ ID NOS: 11, 12, 16, and 17 are assumed to be human.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) in response to this Office Action.

Applicant's cooperation is requested in identifying and correcting any other instances of noncompliance with the requirements of 37 CFR 1.821 – 1.825.

6. Applicant's claim for domestic priority under 35 U.S.C. 120:

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the priority application USSN 09/244,448 disclosed an amino acid sequence which has 14 fewer amino acids that the instantly recited SEQ ID NO:17, and as such, any antibody that binds to the polypeptide of the priority application would necessarily bind to the larger polypeptide of the instant claims.

This is not found persuasive, because the instant claims are broader in scope than the disclosure of the priority application.

Therefore, it is maintained that claims 35 – 44 and 46 – 54, which read on SEQ ID NOS: 16 or 17, have the priority of the filing date of USSN 09/264,527, i.e. 03/08/1999.

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

7. Applicant's IDS, filed 06/16/2006, is acknowledged, and has been considered.

Further, Applicant's submission of copies of references cited on IDS documents filed 05/16/2005 is gratefully acknowledged. The references have been considered. Previously considered references have been lined through to avoid duplication.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 34, 36, 38 – 40, and 46 – 54 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 38 - 40 and 47 stand rejected for the reasons of record, because they are indefinite in the recitation of "polypeptide of Figure ...," as it is unclear whether the intended scope is that of closed language (e.g. "consisting of") or open language (e.g. "comprising").

B. Claims 34, 36, 38 – 40, and 46 – 54 are indefinite in the recitation of "a polypeptide as set forth in SEQ ID NO:12," or "a nucleic acid as set forth in SEQ ID NO:11," because it is unclear whether these sequences are of human of murine origin, as discussed in section 5B above. For examination purposes, it is assumed that these sequences are human.

Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

10. Claims 37 – 44 and 48 – 54 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

The specification does not appear to provide an adequate written description of an antibody which binds both human (SEQ ID NO:17) and mouse (SEQ ID NO:7) B7RP1 polypeptide (claim 37, and claims dependent thereon).

It is noted that claims 38 – 44, dependent on claim 37, have been inadvertently omitted from the rejection of record (Office Action mailed 08/08/2005, section 11).

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that original claim 13 and specification at pages 49 – 50 show that the disclosure contemplates that an antibody may react with more than one distinct B7RP-1 polypeptide, such as, for example, murine and human polypeptides.

This is not found persuasive, because the disclosure and original claims, while providing support for antibodies reacting with human and mouse B7RP-1 polypeptides in the alternative, does not provide sufficient support for an antibody that reacts with both human and mouse B7RP-1 polypeptides.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

11. Claims 42 and 43 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment does not point out where the support for the newly added limitations comes from, and the specification as-filed or original claims do not appear to provide adequate written description of the following limitations: "an agonist antibody that increases B7RP-1 mediated immune costimulatory activity," and "an antagonist antibody that decreases B7RP-1 mediated immune costimulatory activity"

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

12. Claim 44 stands rejected, and claims 42 and 43, as amended, are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for an anti-B7RP1 antibody which inhibits B7RP1-induced T cell proliferation, does not

reasonably provide enablement for an anti-B7RP1 antibody which inhibits, increases, or decreases immune costimulatory activity, as generically recited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the B7RP-1 polypeptide, when tested *in vivo*, was shown to enhance immune responses as evidenced by more severe arthritis in mice (Example 18), and to stimulate cytolytic T cells and cellular immune functions to retard the growth of an immunogenic tumor (Example 20).

This is not found persuasive, because in the highly unpredictable art of antibody therapy, the effect of administration of a polypeptide is not seen as sufficiently predictive of the effect of the corresponding antibody, as instantly claimed. Since the efficacy of therapeutic antibodies can be species- and model-dependent, it is not clear that reliance on the experimental observations in the results obtained using the B7RP-1 polypeptide described in the instant specification provide sufficient basis for employing the claimed antibodies for inhibiting, increasing, or decreasing immune costimulatory activity. For example, Blazar et al. (J. Immunol., 1996, 157: 3250 – 3259; see entire document, in particular, e.g. page 3257, column 2 first paragraph) disclose that issues such as tissue distribution, half-life, affinity and avidity obtained with various antibodies and polypeptides targeting costimulatory molecules might prove to be highly important in achieving a therapeutic effect, and any conclusion regarding the efficacy of costimulatory modulation should be interpreted in light of the specific reagent used (Blazar et al., see page 3257, column 2, paragraph 1). Therefore, there is no evidence that the effect of the B7RP-1 polypeptide in the animal models used in the experiments disclosed in the specification would be predictive of the effects of the antibodies, as encompassed by the claims.

Therefore, the rejection of record is maintained essentially for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent, and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 33 – 54 are provisionally rejected on the ground of nonstatutory **obviousness-type double patenting** as being unpatentable over claims 13 – 18 of copending Application USSN 11/359,254. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same antibodies to B7RP-1 polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 33 – 54 are directed to an invention not patentably distinct from claims 13 – 18 of commonly assigned USSN 11/359,254, for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned USSN 11/359,254, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

16. Conclusion: no claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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August 18, 2006

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8/18/06